## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

: Malone et al.

Serial No.

: 10 / 780,182

Filed

: February 17, 2004

Title

Frozen Aerated Product

Group

: 1761

Examiner

Maureen Donovan

## **DECLARATION**

I, LOYD WIX, declare and say as follows:-

- I am a food scientist working for Unilever Research & Development Colworth, Ice Cream Global Technology Centre, Sharnbrook, UK. I have a BSc in Food Science (1985) from the Faculty of Agriculture, University of Nottingham, UK and an MSc in Process Biotechnology (1986) from the Department of Chemical Engineering, University of Birmingham, UK. I have been employed by Unilever since August 1988, where my field of expertise has been ice cream. I have worked on a variety of formulation and process orientated research projects resulting in new technological implementation in factories and new product launches in the market place based on these technologies. I have 3 patents granted by the US PTO and a further 1 granted by the European Patent Office. My current job title is Lead Ice Cream Formulations Technologist.
- 2. I am an inventor and applicant of patent application serial No. 10/780,182 (hereinafter referred to as "the present application").
- 3. I have read and I am familiar with the present application.
- 4. I have also read US Patent No. 4 452 824 (Cole et al.) which relates to soft frozen dessert formulations. I am advised that the Examiner has referred to runs #89, 90, 93 and 85 as shown in Table 2 of Cole et al. and stated that:

'The applicant has submitted that Runs # 89, 90, 93 and 85 as shown in Table 2, Columns 7 and 8, have a number average molecular weight of 297, 299, 310 and 290 respectively. However, no information, evidence or explanation as to where these numbers were

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generated from has been presented. Therefore the arguments are not deemed persuasive. More convincing evidence is necessary to show what the number average molecular weights of these runs are. It is suggested that calculations or explanations be submitted. The examiner has attempted to calculate the number average molecular weight of each of the components and the equations presented by the applicant in the specification on page 4. However, the molecular weight of the higher saccharides is unknown, and therefore the calculations were not able to be completed. The examiner performed a back calculation for each run of Cole, using the number average molecular weight as recited by the applicant for each run in the arguments on page 5 and the known weight and molecular weight of each of the components, in order to determine what the molecular weight of the higher saccharides is. In each back calculation for each run, a different molecular weight was determined for the higher saccharides. It is not appreciated why the molecular weight for the higher saccharides would change between runs. Therefore the number average molecular weights as submitted by the applicant are not deemed persuasive, due to the lack of evidence or explanation as to how the numbers were generated.'

- 5. Cole (US 4 452 824) sets out the freezing point depressants of runs 89, 90, 93 and 85 in two different ways: by ingredient (Table 1) and by saccharide composition (Table 2). The Examiner correctly points out that Table 2 does not state the molecular weight of the higher saccharides, and therefore it is not possible to calculate the number average molecular weight from this table. Back-calculating the molecular weight of the higher saccharides from the applicant's value results in different molecular weight for each run for two reasons. Firstly the higher saccharides are obtained from different amounts of three different corn syrups in each run (each of which has a different saccharide composition). Secondly sorbitol has a molecular weight of 182, whereas in Table 2 it is included with monosaccharides which have a molecular weight of 180. A calculation based on table 2 alone cannot take account of this, whereas the applicant's calculation (as set out below) does.
- 6. As a result it is necessary to perform the calculations on the basis of Table 1.
- 7. Run 89 contains whole milk, cream and non-fat dry milk solids, 36DE corn syrup and dextrose.

## Lactose

The whole milk, cream and non-fat dry milk are the only source of lactose and do not contain any other saccharides; the lactose content of the ice cream is 5.5%, as set out in Table 2. Lactose has a molecular weight of 342.

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36DE corn syrup provides a mixture of dextrose, maltose and higher saccharides. However, it is not necessary to separate the corn syrup into its components to calculate its molecular weight since the equation at the bottom of page 4 of the specification can be used. 36 DE corn syrup has a molecular weight of 18016/36 = 500.4. The 36 DE corn syrup is 80% solids. Thus of the 16.85% in the mix, 13.42% (= 0.8 \* 16.85) is the saccharides while the rest is water.

## **Dextrose**

Dextrose has a molecular weight of 180. It is supplied as a monohydrate which contains 91.5% dextrose and 8.5% water. Thus of the 10.44% added to the mix, 9.55% (= 0.915 \* 10.44) is dextrose. (This is less than 11.45% stated in Table 2 since the latter also includes dextrose from the 36 DE corn syrup).

The saccharide content of run 89 is therefore as set out in the following table:

Ingredient	Molecular	Amount	% solids	Actual	Number of moles
	weight (Mi)	including water	·	amount (Wi)	(Ni = Wi/Mi)
Lactose	342	5.5	100	5.50	0.0161
36 DE CS	500.4	16.85	80	13.48	0.0269
Dextrose	180	10.44	91.5	9.55	0.0531
			Total	28.53	0.0961

The number average molecular weight is given by the equation on page 4 line 10 of the present application:  $Mn = \Sigma Wi / \Sigma (Wi/Mi) = 28.53 / 0.0961 = 297$ 

8. The calculations for runs 90 and 85 respectively are set out in the tables below.

Ingredient	Molecular	Amount	% solids	Actual amount	Number of moles
	weight (Mi)	including water		(Wi)	(Ni = Wi/Mi)
Lactose	342	5.5	100	5.50	0.0161
36DE CS	500.4	16.85	80	13.48	0.0269
Sorbitol	182	9.55	100	9.55	0.0525
			Total	28.53	0.0955

Run 90 Mn = 28.53 / 0.0955 = 299

Ingredient	Molecular	Amount	% solids	Actual amount	Number of moles
	weight (Mi)			(Wi)	(Ni = Wi/Mi)
Lactose	342	6.5	100	6.50	0.0190
36DE CS	500.4	10.39	80	8.31	0.0166
Dextrose	180	9.48	91.5	8.67	0.0482
Sucrose	342	5.18	100	5.18	0.0151
			Total	28.66	0.0989

Run 85 Mn = 28.66 / 0.0989 = 290

9. Run 93 uses a high fructose corn syrup. Since the DE of this is not given in Cole et al., it is necessary to make an assumption about its molecular weight. The calculations were performed assuming the "worst case" scenario, i.e. the high fructose corn syrup has the lowest possible molecular weight, so that the overall average molecular weight is also the lowest. This can be done in two ways.

The first assumes that the saccharides in HFCS consist only of fructose (molecular weight 180). This results in the following calculation

Ingredient	Molecular	Amount	% solids	Actual amount	Number of moles
	weight (Mi)	including water		(Wi)	(Ni = Wi/Mi)
Lactose	342	6.5	100	6.50	0.0190
36 DE CS	500,4	10.39	80	8.31	0.0166
50 DE CS	360.3	4.26	81	3.45	0.0096
HFCS	180	7.29	71	5.18	0.0288
Sucrose	342	5.18	100	5.18	0.0151
			Total	28.62	0.0891

Mn = 28.62 /0.0891 = 321

The second is based on Table 2, and assumes that all the higher saccharides are trisaccharides (i.e. no saccharides with a degree of polymerisation of 4 or higher). This results in the following calculation:

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Saccharides	Molecular	Amount	% solids	Actual amount	Number of moles
	weight (Mi)			(Wi)	(Ni = Wi/Mi)
Mono	180	6.21	100	6.21	0.0345
Di	342	14.32	100	14.32	0.0419
Higher	504	8.07	100	8.07	0.0160
			Total	28.60	0.0924

Mn = 28.62 / 0.0891 = 310

In our earlier response, we quoted the lower of these two values. In fact, both are underestimates since the high fructose corn syrup actually contains some saccharides of higher molecular weight than fructose.

I further declare that all statements made herein of my own knowledge are true and that all 10. statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardise the validity of this application or any patent issuing thereon.

DECLARED at Colworth, UK this day of October 2005

LOYD WIX